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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,303	11/28/2000	Akihiko Sano	0020-4771P	8796
2292	7590	07/28/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			SPEAR, JAMES M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*Ku*

## Office Action Summary

Application No.

09/701,303

Applicant(s)

SANO ET AL.

Examiner

James M. Spear

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
AU 1618

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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The Amendment filed 06 July 2005 has been entered.

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. After further review and consideration it has been determined that the following rejection is required.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujioka et al US 5,851,547 alone. Fujioka et al shows a rod shaped preparation having the same configuration as that of applicants. See figure 1. The preparation may comprise an outermost layer and an inner layer. See figure 2 (B). The preparation may comprise multiple layers and multiple drugs. Column 7, lines 7-9, 53-63. When the

layers are concentric circles it is clearly evident that multiple drugs are present. The reference further teaches an embodiment wherein an outer layer (b) as described in the abstract is absent. See example 1 that shows a comparative representation of a matrix formulation (1) and the invention (2). The results of the comparison are shown in figure 3. Fujioka et al shows the same rod shaped layered formulation comprised of water soluble drugs and non-degradable hydrophobic polymeric materials. In particular the reference shows applicants' identical silicones such as Silastic Medical Grade ETR Elastomer Q7-4750 and MDX 4-4210 Medical Grade Elastomer. Column 5, lines 50-64. Particular water soluble drugs are shown in column 6, line 35 through column 7, line, 9. While the prior art claims an outer layer comprised of a biocompatible hydrophobic polymer that is free of any drug the prior art also recognizes the significance of not having such a layer as explained above. The reference suggests that elimination of the layer would provide a more rapid release of the drug. Column 10, lines 1-12.

Applicants claims eliminate the outer layer of Fujioka et al. formulation. The Omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031(Bd. Pat & Inter. 1989). *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965). *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). MPEP 2144.04 II A.

It would be reasonable to remove the outer layer of Fujioka et al because different drugs require different release profiles. It would have been obvious to one of ordinary skill in the art to delete the outer layer (b) of Fujioka et al to modify the release of a multilayered rod shaped drug formulation. The motivation being a desire to tailor a

drug formulation to fit specific release profiles for different drugs and provide a more rapid initial release of one drug while providing a different release rate for another drug in order to achieve the optimum therapeutic response. Column 5, lines 10-15.

Claims 1-8 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*James M. Spear*

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PRIMARY EXAMINER

AU 1618

7-23-2005